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Statement of Dr. Lauren Smith, Interim Commissioner
and Dr. Madeleine Biondolillo
Director of the Bureau for Health Care Safety and Quality
Department of Public Health Press Conference
Sunday, October 28, 2012

Good afternoon.

I'm Dr. Lauren Smith, interim commissioner of the Massachusetts Department of Public Health. I want to thank Governor Patrick and Secretary Bigby for putting their trust in me to lead the department at this critical time. I know that we face great challenges. At the same time, though, we have a rare opportunity to create meaningful change. I have dedicated my career as a doctor and a public servant to protecting the public's health. My experience, passion and commitment will inform the decisions I make to move this department forward. It will also guide me as we provide strong oversight of the pharmacy compounding industry and keep the people we're charged with protecting safe.

The Department of Public Health is executing a series of aggressive and necessary actions to protect public safety and enhance oversight of this industry following the national meningitis outbreak.

As our joint investigation with our federal partners into NECC and Ameridose continues, we have launched a series of immediate, on-site inspections of other compounding pharmacies in Massachusetts that prepare sterile injectable medications. To supplement these efforts, DPH is in the process of bringing on five additional inspectors to the Board of Pharmacy to ensure that we have the resources to execute on this plan. As our current investigators are engaged in the ongoing investigations of NECC and Ameridose, additional staff will be crucial in expediting the process of unannounced inspections. We have additional inspectors starting this week, as temporary staff, to ensure completion of these unannounced inspections by January 1, 2013. We will make their findings available as part of our larger efforts to ensure that the board maintains

the trust of the public.

Now, I'm going to turn it over to Dr. Madeleine Biondolillo, director of the DPH Bureau of Healthcare Safety and Quality to provide an update on the inspection process.

[Dr. Biondolillo Speaks]

On Tuesday October 23rd, we conducted an unannounced inspection of Infusion Resource, a compounding pharmacy in Waltham that prepares sterile, injectable medications. Consistent with our regulations, the pharmacy was last inspected when it opened in December 2009 and was the subject of a comprehensive review. At the time, it was found to be in compliance with all requirements for sterile compounding and since then, no complaints have been received.

Upon arrival last week, however, inspectors noted significant issues with the environment in which medications were being compounded, which has called into question the company's compliance with nationally-accepted pharmacy standards and Massachusetts regulations. Due to a variety of notable findings regarding the conditions of the medication production areas, inspectors expressed concern for the sterility of products.

Additionally, there was an adjacent space set up for giving patients intravenous medications on-site. Infusion Resource does not have an appropriate clinic license to conduct these activities, which is a violation of state regulations.

On October 23rd, the Board of Pharmacy issued an immediate cease and desist and quarantine notice, preventing Infusion from dispensing any drugs or medications. And this weekend, DPH secured the voluntary surrender of Infusion's Pharmacy License.

Infusion Resource's primary business is supplying specialized medications for patients after they've been discharged from a hospital. Infusion has agreed to contact all of its approximately 40 patients and their prescribing physicians to request that any outstanding medications that the patients have on-hand be returned. Infusion Resource is working with other providers to ensure that the continuity of care for patients is not disrupted.

Please note that these actions are precautionary and there is no current evidence of contaminated products at Infusion Resource. This investigation is still in its preliminary stages and we are working with Infusion Resource's manager of record, who is a former employee of Ameridose,

to obtain additional information.

[DR. SMITH RETURNS]

Thank you Dr. Biondolillo. We will continue our aggressive unannounced inspections of compounding pharmacies while also focusing on our ongoing investigations of NECC and Ameridose.

It is crucial that the Board of Pharmacy earns the public's trust throughout this process. Later today, we will release those Board meeting minutes from the last 10 years that refer to NECC, Ameridose or Alaunus. Some of these minutes call into question whether Board Member Sophia Pasedis, the manager of record at Ameridose, recused herself from Ameridose and NECC matters before the Board. Although Ms. Pasedis has claimed that she did, in fact, recuse herself, which is consistent with the Board staff's recollection, there is no definitive proof that she did so on certain occasions. She is also the pharmacist of record at Ameridose, meaning she is responsible for pharmacy operations and conformance with all laws and regulations pertinent to the practice of pharmacy and distribution of drugs. Ameridose has ceased distribution of all products and is currently under investigation by DPH and FDA officials. Given the ongoing investigation, we believe it is in the best interest of the Board to have Ms. Pasedis step down. Thus far, she has declined to do so. Ms. Pasedis's term expires next month. We are considering what actions to take in the interim.

Finally I want to apprise you of some upcoming actions.

At Governor Patrick's direction we are filing regulations to require compounding pharmacies in Massachusetts to submit frequent reports of production, volume and distribution of sterile, injectable medications. This reporting will allow us to better identify large-scale operations acting more as a manufacturer, which requires federal licensure and additional scrutiny.

We are also launching a special commission to examine best practices in other states and potential changes to state law or regulations to help us keep pace with an evolving industry and close the regulatory grey area that exists between state and federal oversight.

Our commitment to public safety and public health is unwavering. We will announce the commission chair and file the emergency regulations in the coming days. And we will provide you with regular updates on these and all other developments as our work continues.

Now Dr. Biondolillo and I are happy to take your questions.

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